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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,715	01/22/2004	Kristian DiMatteo	706182-2001	5203

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BINGHAM MCCUTCHEN LLP
2020 K Street, N.W.
Intellectual Property Department
WASHINGTON, DC 20006

EXAMINER

GRAY, PHILLIP A

ART UNIT	PAPER NUMBER
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3767

MAIL DATE	DELIVERY MODE
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09/06/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/762,715	Applicant(s) DIMATTEO ET AL.	
	Examiner PHILLIP GRAY	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6/2/2011</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to applicant's communication of 6/8/2011.
Currently new claims 25-33 are pending and stand rejected below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dryden (U.S. Patent 5,125,893) in view of Schmidt (U.S. Patent 5,249,598).

Dryden discloses a system for injection of fluids into a patient comprising a catheter (17/11), a valve housing (22) comprising an inlet (nearer 23), outlet (nearer 21),

slitted flow control membrane (valve near 23), bypass element (28/31), and overpressure control element (35-36). Concerning claims 26-27 and the distance and rounded tip see figures 1 and area near 31, note distance maximum of valve greater than diameter and tip is rounded (31).

Concerning Dryden, the over pressure control element (35 or 36) would be fully capable of being adapted to maintain a pressure of fluid within the connector below a predetermined threshold (as described in column 2 lines 45-56) and be a pressure relief valve.

"The amount of vacuum applied can be controlled by the valve 36. This can be a conventional roller valve of the type used on intravenous feeding tubes. Other valve types might be used. Another example is the squeeze-to-open, automatic-closure, type. Similarly, the amount of irrigation fluid supplied can be controlled by valve 35."

It is examiners position that these valves since they regulate the amount of gas or liquid through the system would be a type of "overpressure control element". By controlling the amount and regulating (also the teaching that it could be other valves like squeeze to open, automatic-closure, ect), these valves would be a type of pressure relief valves.

Although it is examiners position that Dryden discloses overpressure control element or "pressure relief valve" adapted to maintain a flow and pressure of fluid within the connector below a predetermined threshold (valve 35/36 i.e. and its function); but in

the alternative it would have been an obvious modification thereof and well known to a person having ordinary skill in the art to construct the valve (35) to be an “over pressure control element” to allow a safe pressure level of fluid to reach a patient, and be a pressure relief valve. Such valves are well known in the art. It is examiners position that when one regulates fluid or a gas through a system, the pressure should be maintained within an acceptable range. In order to regulate it at the upper range a pressure relief valve is one component known to be used by a person having ordinary skill in the art at the time of the invention.

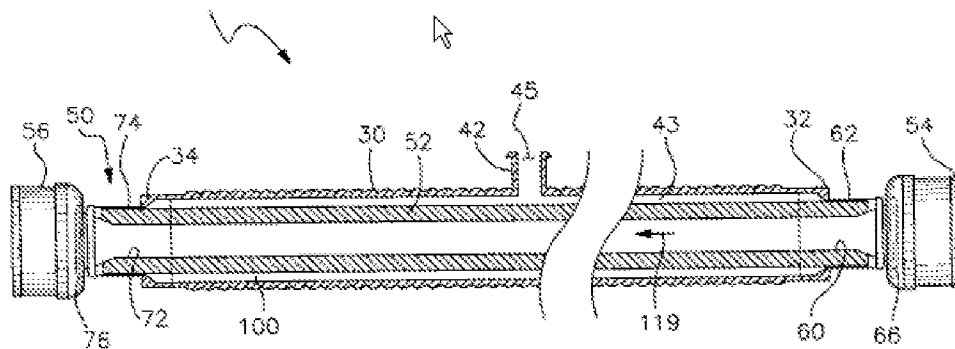
Dryden discloses the claimed invention except for the spring loaded pressure relief valve. Schmidt teaches that it is known to use spring loaded pressure relief valve as set forth in paragraphs at columns 1-3 to provide an efficient and effective means for controlling fluid and pressure along a pathway. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Dryden with spring loaded pressure relief valve as taught by Schmidt, since such a modification would provide the system] with spring loaded pressure relief valve for providing an efficient and effective means for controlling fluid and pressure along a pathway.

Claims 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dryden (U.S. Patent 5,125,893) in view of Schmidt, in further view of Armenia et al. (U.S. Patent 6,446,671).

Concerning claims 29-30; Dryden in view of Schmidt discloses the claimed invention except for the controlled failure element and fluid capture jacket (being an

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extension tube and having a external collection jacket disposed around with a space between). Armenia teaches that it is known to use an controlled failure element and fluid capture jacket being an extension tube and having a external collection jacket (Armenia 30) disposed around as set forth in paragraphs at columns 3-4 to provide a controlling means to contain a spill or rupture within the device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Dryden in view of Schmidt with an controlled failure element and fluid capture jacket as taught by Armenia, since such a modification would provide the system with the controlled failure element and fluid capture jacket for providing a controlling means to contain a spill or rupture within the device.



Concerning claims 31-32 Dryden in view of Schmidt discloses the claimed invention except for the catheter size French 3 pressure approximately 125 PSI and inner diameter less than approximately 0.56mL/sec or size 7 French pressure approximately 330 PSI and inner diameter less than approximately 8.78 mL/sec.

It would have been obvious to one having ordinary skill in the art at the time the craft the catheter in these sizes with the following pressure and diametersi., since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233 (CCPA 1955), and since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). These sizes of catheters PSI pressures and diameters are well known to PHOSITAs and are routine sizes/pressures/and diameters known in the catheter arts for there intended usages.

Concerning claim 33 see figure 1 and the spatial/operational orientation of the bypass device, overpressure control device, catheter, valve, slit and flow control membrane.

Response to Arguments

Applicant's arguments with respect to newly added claims 25-33 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to u whose telephone number is (571)272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phillip Gray/
Examiner, Art Unit 3767

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3763